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SUBJECT: NEW HEALTH MINISTER PROMISES REVIEW ON COMPULSORY
LICENSES

11. (SBU) Summary: Thailand's new pro-business government has quickly announced plans to review the previous administration's controversial policy of issuing compulsory licenses (CLs) on patented medicines. In his last days in office the outgoing Health Minister paved the way for continuation of the CL policy, signing four more CLs on cancer drugs, following on three other CLs issued over the previous 16 months. The new Minister promised to review the legality of procedures followed and the appropriateness of the policy. He has suggested that doing away with CLs is needed to stave off trade sanctions from a negative Special 301 review. At the former Minister's request, a WHO-led delegation is also carrying out a review of the CL procedures but said it does not plan to issue a judgment on whether procedures in WTO rules and Thai law were followed correctly. End summary.

12. (SBU) On his first day in office on February 7, newly inaugurated Minister of Public Health Chaiya Sasomsab promised to review his predecessor's policy of overriding patents on pharmaceutical products. In a February 12 Cabinet meeting, PM Samak approved the review and instructed Deputy Prime Minister and Commerce Minister Mingkwan Saengsuwan to meet with MFA and Health Ministry officials to discuss the CL policy and review past decisions. Minister Chaiya indicated the review would be completed by March 30.

13. (SBU) During his 16-month term in the coup-installed government, former Minister Mongkol na Songkhla issued three compulsory licenses (CLs) on patented anti-retrovirals (for AIDS treatment) and a blood thinner, citing unreasonably high prices and the inability of patients to afford the medicines. In his closing days in office, Mongkol signed authorizations for CLs on four more drugs used to treat cancer patients, though the Ministry has yet to implement the licenses by importing generic copies. The four drugs include Novartis' breast cancer drug letrozole and its leukemia and gastrointestinal cancer drug imatinib, Sanofi-Aventis' breast and lung cancer drug docetaxel, and lung cancer drug erlotinib from Roche. (Note: U.S. companies manufacture two of the three drugs originally affected by CLs, the most recent three are made by European pharmaceutical companies.) Although MOPH issued a CL for imatinib, the Ministry stated that it would not exercise the CL unless there were access problems under Novartis' Glivec International Patient Access Program. Under the GIPAP program, MOPH negotiated a deal for free access to imatinib for any Thai patient who has an income of less than 1.7 million Baht per year. The only CL implemented thus far is for Merck's efavirenz, though Merck claims that the number of patients using the generic product is a small fraction of the number that Minister Mongkol claimed would be served. Other already issued CLs may be difficult to implement. It is not clear whether a generic exists for Abbott's Aluvia, and Sanofi-Aventis is engaged in a protracted legal battle in both

Thailand and India over implementation of the CL for Plavix.

14. (SBU) Although Minister Chaiya was not specific on the scope of the upcoming review, the pharmaceutical industry expects it will consider whether to proceed with the three CLs on cancer drugs, but not necessarily on whether to withdraw the three CLs already implemented. Chaiya earlier told journalists that he would review whether the Ministry had followed the correct procedures in issuing the compulsory licenses, saying, "It might have been a politically correct decision, but not legally correct." Chaiya reportedly instructed health officials to determine whether the Cabinet had approved the policy before the compulsory licenses had been issued, or had been notified after the fact. Chaiya also said he would like to determine whether the number of patients needing the medicines and their access to them necessitated issuing CLs. Representatives of drug manufacturers would be invited to discuss the legal aspects of the decision as well as the commercial impact. As reported in the press, health activists met with the new Minister on February 8 and protested the plans to review the policy, saying that Thai law had been appropriately followed. More protests have followed on a daily basis.

15. (SBU) The Ministry of Public Health (MoPH) under the former Minister posted a 56-page report on its website explaining the decision behind the three additional CLs on cancer drugs, citing 30,000 deaths annually from cancer in Thailand and the high expense of the drugs used to treat patients. The report paints a portrait of extensive efforts to negotiate transparently with pharmaceutical companies to reach agreement on prices, and frequent consultation with other RTG ministries. Industry takes a different point of view, claiming that the MoPH did not negotiate in good faith, refusing to budge from its initial demand of companies to lower their prices to within five percent of generic prices. MoPH's estimate of the number of patients that could be treated with

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generic medicines is substantially higher than industry's estimates.

New government takes new tack

16. (SBU) As a newcomer to the health field, Minister Chaiya's own views on the appropriateness of the previous government's CL policy are unknown. The coalition leader People Power Party has espoused a pro-business philosophy, has promised to review and revise some of the previous government's other controversial economic policies, and may do the same with CLs. In Chaiya's recent statements he has suggested replacing the CL policy with an increased budget to cover essential drugs for those who cannot afford them. Minister Chaiya recently cited concerns over the U.S.'s upcoming Special 301 review on Thailand's protection of intellectual property as a motivation for initiating the CL review. Local press reported that Chaiya named the CLs as the main reason for last year's downgrading of Thailand to the Special 301 Priority Watch List, and blamed that downgrading on Thailand's loss of certain trade benefits of the U.S. Generalized System of Preferences (GSP) program. He said he was concerned that the budget savings from using CLs would not match the losses in trade benefits.

17. (SBU) Chaiya's characterizations of last year's changes in the GSP program and the PWL decision are inaccurate, but his views are widely shared by the Thai public and within the RTG. Despite numerous meetings between U.S. Embassy officials and Ministry of Commerce officials explaining the graduation process in the GSP program and its lack of a relationship to the Special 301 decision, officials at the Department of Intellectual Property (DIP) continue publicly to cite CLs as a prime reason behind both the PWL decision and Thailand's loss of GSP benefits.

WHO does its own review

18. (SBU) At the request of the former Health Minister, a delegation led by the World Health Organization and joined by officials from the WTO, UNDP, UNCTAD and academic advisors visited Thailand last

week to review the procedures followed in issuing and implementing compulsory licenses. In a February 6 meeting with Embassy officials from the U.S., EU, Switzerland, Australia and Brazil, the delegation said their mission was guided by World Health Assembly resolution 60.30 to provide technical and policy support on flexibilities provided in WTO rules to promote access to medicines. Although the delegation said they would be providing policy advice, WHO's Dr. German Velasquez said they could not comment on Thailand's domestic matters, and declined to describe their findings thus far on the procedures followed by Thailand in issuing the CLs. The delegation said they would be issuing a report "within ten days," but that it would be released only to the RTG and not to other WHO member governments. Delegation members insisted their report would be factual and would not judge the appropriateness of the policy one way or the other. Comment: Without a wider distribution of the WHO report, there is concern that the report may be selectively quoted by partisans to manipulate the CL debate. End comment.

¶9. (SBU) In addition to RTG health officials, the delegation also met with health activists and separately with the pharmaceutical industry. Industry representatives spoke positively about the meeting as the delegation allowed substantial time for them to detail their complaints of the RTG's lack of transparency, communication and due process during the CL process. However, industry was unable to elicit much information about the progress of the delegation's review. Privately, one of the delegation's members said there were notable discrepancies between industry's and the RTG's recounting of events.

Next steps

¶10. (SBU) The European Union's representative informed Embassy that his mission had drafted a letter for EU Commissioner Mandelson's signature requesting the new Health Minister to "take a fresh look" at the CL policy. The local EU rep has suggested that the U.S. coordinate on a joint letter to the Minister or to send its own separately.

¶11. (SBU) In a meeting with DCM on February 13, representatives from U.S. pharmaceutical companies said they hoped the new administration would continue the Joint Committee between industry and the Ministry of Public Health to work on improving public health, including access to medicines. Future meetings would depend

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on a green light from the Minister. Industry also plans more public relations activities, including a life science innovation conference. Companies are preparing to work more closely with local press, and will introduce a set of "advertorials" explaining the health contribution to Thailand of a number of drugs.

Comment

¶12. (SBU) It is apparent that before leaving office former Minister Mongkol did all he could to force the hand of the new government on the CL issue. However, the new government appears keen to ease the minds of a rattled business community, and has placed among its top priorities addressing issues that concerned foreign investors during the coup government. The government may quietly shelve the compulsory license policy as a step in that direction. However, it may not withdraw the three compulsory licenses that have already been implemented, which were among the few popular actions taken by the last government.

JOHN